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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|--------------------------|---------------------|------------------|
| 10/796,747      | 03/09/2004  | Dorothea Zucker-Franklin | 57953/1201          | 2516             |

7590 04/23/2007  
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| EXAMINER |
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KIM, SUN U

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| ART UNIT | PAPER NUMBER |
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1723

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/23/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

|                              |                        |                           |  |
|------------------------------|------------------------|---------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>       |  |
|                              | 10/796,747             | ZUCKER-FRANKLIN, DOROTHEA |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>           |  |
|                              | John Kim               | 1723                      |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 March 2007.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.  
4a) Of the above claim(s) 7-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4/1/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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1. Applicant's election with traverse of Group I (claims 1-6) in the reply filed on 3/28/07 is acknowledged. The traversal is on the ground(s) that the restricted groups are closely related and, therefore, would require common areas of search and consideration. This is not found persuasive because the inventions of groups are distinct from each other for reasons cited in pages 2-3 of the previous office action mailed 1/30/07 and the inventions have acquired a separate status in the art in view of different classification such that there would be serious burden on the examiner if restriction is not required.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in the reply filed on 3/28/07.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meynier, Jr (US Patent No. 2,364,866) in view of Pall et al (US Patent No. 5,229,012) and Arch journal article (Arch Dis Child 2001; 84:381-382 (May)). Meynier, Jr. teaches a nipple shield device comprising a base (2) and a protrusion (4) that is shaped to conform to a mammalian female areola and nipple, wherein the protrusion (4, 8) has one or more holes (9) permitting intake of breast milk by an infant (see figures 1-3; col. 1, lines 1-3; col. 1, line 45 – col. 2, line 7). Claims 1-4 essentially differ from the nipple shield device in reciting leukocyte filter or filters attached

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inside and along the protrusion. Arch journal article teaches that HIV viruses are transmitted to infants via breast feeding and possible removal of virus by filtering (see pages 2-3). Pall et al teach leukocyte filter of fibrous web or webs (12) contained in a housing (11) via an interference fit (see figure 1; col. 14, lines 41-55; col. 17, lines 28-52; col. 19, lines 13-19). Pall et al further teaches that removal of leukocytes is regarded as beneficial since some viruses including HIV virus are resident in the leukocytes (see col. 1, lines 52-64). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the nipple shield of Meynier, Jr. to include leukocyte filter of fibrous web or webs in interference fit with the inside surface of the nipple shield to remove leukocytes from breast milk to prevent transmission of HIV viruses to an infant as suggested by Pall et al and Arch journal article.

Regarding claims 7-8, Meynier, Jr. teaches that the nipple shield is made of flexible Material including natural rubber, synthetic rubber or the like (see col. 1, lines 45-50).

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. References cited in PTO-892 teach various nipple shield devices or breast pumps.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is 571-272-1142. The examiner can normally be reached on Monday-Friday 7 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven Griffin can be reached on 571-272-1189. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**John Kim**  
**Primary Examiner**  
**Art Unit 1723**

JK

4/18/07